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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/711,156	08/27/2004	Bryan E. GARNER	5233.012.NPUS01	5155

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NOVAK DRUCE & QUIGG, LLP
1300 EYE STREET NW
SUITE 1000 WEST TOWER
WASHINGTON, DC 20005

EXAMINER	
SHAW, AMANDA MARIE	

ART UNIT	PAPER NUMBER
1634	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action Before the Filing of an Appeal Brief	**Application No.** 10/711,156	**Applicant(s)** GARNER, BRYAN E.
	Examiner Amanda M. Shaw	**Art Unit** 1634

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 02 April 2007 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☒ The period for reply expires 5 months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☒ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: *See Continuation Sheet*. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☒ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: *none*.
   Claim(s) objected to: *none*.
   Claim(s) rejected: *1-11,16 and 17*.
   Claim(s) withdrawn from consideration: *none*.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). _____
13. ☐ Other: _____.

DIANA JOHANNSEN
PRIMARY EXAMINER

Continuation of 3. NOTE: The proposed amendment to Claim 1 raises new issues because the scope of the claim has changed. Previously the claims were drawn to a method for "assessing the relative quantity of a viable microorganism of interest that is present in or on a food product". However now the claims recite a method for "assessing the relative quantity of a viable microorganism of interest per known quantity of a food product that is in or on a food product". Determining the relative quantity of a microorganism per quantity of food would require additional method steps (i.e. such as further calculations) that are not recited in the claims. Additionally these amendments raise new issues under 35 USC 102 and/or 103 necessitating a new search. Particularly the claims have not previously required determining the quantity of microorganisms per known quantity of food. For these reasons further search and consideration would be required..

In the response filed April 2, 2007, Applicants argued the new matter rejections. The arguments have been fully considered and if this amendment had been entered the rejection over the phrase "obtaining a liquid suspension sample" would have been dropped. However the rejections over "preparing a series of progressively dilute samples" and utilizing an estimation model" would have been maintained. It is noted that the Applicants have support for performing "serial dilutions" (See example 5). However the specification does not teach "progressive dilutions" and it is unclear if "progressive dilutions" are equivalent to "serial dilutions". Further it is noted that the Applicants have support for using the Most Probable Number method to determine the concentration of the organisms. However the specification does not provide support for using any "estimation model" to determine the concentration of the organisms. Additionally it is noted that the Applicants have provided copies of the Cochran and Peeler references, and appear to be relying on the references as providing bases for limitations in the claims. However, while these references are mentioned in the specification (Page 14), the references were not incorporated by reference, and cannot be relied upon to overcome the instant rejections. Further it is noted that these references have not been properly cited in an IDS.

The Applicants also argued the rejections made under 35 USC 112 2nd paragraph. The arguments have been fully considered but have not been found persuasive. The Applicants argued that the phrase "relative quantity" is in relation to a known amount of food product and that one of skill in the art could determine the scope of the claims. This argument was not found persuasive. The phrase "relative quantity" is indefinite because it is unclear if this means that the "exact quantity" of microorganisms in the sample is being determined or if some other quantity is being determined. For instance if the "exact quantity" is not being determined, it is unclear how much more or how much less is actually being determined. It is also noted that the applicants have amended the claims by adding the phrase "per known quantity of a food product" to clarify the phrase "relative quantity" however since this amendment has not been entered the phrase "relative quantity" is still unclear. Further with respect to the rejection made over the phrase "substantial entirety" the Applicants argue that one of skill in the art would understand that an insignificant amount of microorganism may not be transferred. This argument was not found persuasive. The phrase "substantial entirety" is indefinite because it is unclear as to what amount is considered the "substantial entirety". For example its unclear if there were 100 organisms in a sample and only 50%, were transferred would that be considered "substantial entirety" or does a certain amount have to be transferred. With respect to the rejection made over the phrase "recovery media" the Applicants argue that "recovery media" is well known in the art. The argument was not found persuasive. The phrase "recovery media" is not defined in the specification. It is noted that the specification discloses the use of both liquid and solid media however it is unclear if "recovery media" is a certain type of liquid or solid media. With respect to the rejections over the phrase "progressively dilute" it is noted that serial dilutions are supported in the specification however it is unclear if "progressive dilutions" are equivalent to "serial dilutions". Further with respect to the rejections over the phrase "estimation model", the specification has provided one example of an "estimation model" (i.e., MPN). Therefore it is unclear if the claims which recite "estimation model" are limited only to the MPN method or if additional methods meet this limitation.

The Applicants also argued the rejections made under 35 USC 102/103. The arguments have been fully considered but have not been found persuasive. Specifically the Applicant argue that the Begum et al reference does not teach uses an estimation model to determine the concentration of the viable microorganisms based on the results of the PCR analysis. Begum et al teaches the detection of Shiga like toxin producing E. coli in ground beef using the polymerase chain reaction. The PCR products were visualized using agarose gel electrophoresis. Since the claims only require "assessing the relative quantity of a viable organism" and not the exact quantity one would be able to determine just by looking at the gel if the sample contained a little or a lot of the microorganism based on the thickness of the bands. Since the phrase "estimation model" is indefinite, for art purposes this is not given a lot of weight and could be interpreted broadly as just looking at the gel and using the thickness of the bands to "estimate" the amount of microorganisms present. The Applicants also argued that the rejections over Begum et al in view of DesRosier et al were based on hindsight. In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See In re McLaughlin, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). In the instant case the Examiner, did not rely on the Applicants specification, but on the teachings of the references, in concluding that the invention as claimed was obvious. Further it is noted that the claims merely require "utilizing an estimation model to determine the concentration of the viable microorganism of interest present on the food product based on results of the PCR," wherein the "estimation model...is a most probable number method". Thus, the claim as written encompasses, e.g., performing further analysis on the "food product" (such as the analysis of DesRosier) following a determination by PCR that a particular "viable microorganism" is present in the food product. The claim as written does not actually require, e.g., quantitation of PCR products per se, as argued by applicant.

Finally it is noted that Claims 1-3, 7, 9-16, and 37-40 stand provisionally rejected on the ground of nonstatutory obviousness type double patenting as being unpatentable over claims 1-11 and 16-17 of copending Application 10/711156.